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PAPER

	APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
	09/607,602	06/30/2000	Matthew Joseph Doyle	8141	8543
		7590 02/09/200 R & GAMBLE COMP.	EXAMINER		
	INTELLECTUAL PROPERTY DIVISION WINTON HILL BUSINESS CENTER - BOX 161 6110 CENTER HILL AVENUE CINCINNATI, OH 45224			GITOMER, RALPH J	
				ART UNIT	PAPER NUMBER
				1657	
	SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE	

Please find below and/or attached an Office communication concerning this application or proceeding.

02/09/2007

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

: ***		Application No.	Applicant(s)				
	Office Action Commence	09/607,602	DOYLE ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Ralph Gitomer	1657				
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover she	eet with the correspondence ad	Idress			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1))⊠ Responsive to communication(s) filed on <u>12 January 2007</u> .						
·		action is non-final.					
3)							
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4)🛛	Claim(s) 2-4 and 7 is/are pending in the applic	ation.					
•	4a) Of the above claim(s) is/are withdrawn from consideration.						
5)	Claim(s) is/are allowed.						
6)🖂	Claim(s) <u>2-4 and 7</u> is/are rejected.						
7)	') ☐ Claim(s) is/are objected to.						
8)	8) Claim(s) are subject to restriction and/or election requirement.						
Applicati	on Papers						
9)	The specification is objected to by the Examine	r.					
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 							
Attachmen 1) Notic 2) Notic 3) Infor	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4) ☐ Inter Pape	view Summary (PTO-413) er No(s)/Mail Date ce of Informal Patent Application				

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The amendment received 1/12/07 and the IDS received 7/25/06 have been entered and claims 2-4, 7 are currently pending in this application. The claims have been renumbered according to Rule 1.26.

There are many typos in the specification, for example on page 8 with missing letters. Correction is required.

In view of the amendments to the claims and arguments presented, the rejections of record under 35 U.S.C. 102(b) are hereby withdrawn. However, note the new rejection following necessitated by the addition of C reactive protein and apolipoprotein B to the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-4, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Pan, Singer and Tsujita in view of newly cited Mendall.

Pan (WO 97/16159) teaches H2 antagonists including cimetidine may be employed in an oral composition in an amount effective to treat or prevent inflammation in the oral cavity and may also comprise essential oils to act as antimicrobial agents.

Singer (5,364,616) teaches a method for treating or preventing periodontitis comprising topically administering a composition of H2 antagonist in the form of a dentifrice, mouthwash, mouth rinse, mouth spray or dental treatment solution. The compositions may be in the form of a toothpaste, tooth gel, powder, chewing gum and may act as odor masking agents, see column 15 lines 24-60 and claims 9-15. Various forms of the composition are discussed. Additional antimicrobial/antiplaque agents may be included.

Tsujita (JP 04089428), English translation now provided, teaches on page 7 an example of a method of treating periodontitis topically with cimetidine as an active ingredient. On page 10 combining cimetidine with antibiotics is effective.

The claims differ from the above references in that they have been amended to recite the H2 antagonist is effective to decrease systemic blood levels of C reactive protein and apolipoprotein B.

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Mendall teaches on page 1061 column 2 first full paragraph, C reactive protein is raised in periodontal disease. In the abstract C reactive protein concentration is associated with raised apolipoprotein B.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat an oral cavity pathogen induced systemic disease by administering an H2 antagonist topically as shown by each of the above primary references which would then result in decreasing C reactive protein and apolipoprotein B as shown by Mendall because Mendall teaches both C reactive protein and apolipoprotein B are elevated in periodontal disease and other inflammatory conditions. Treating the inflammatory condition would then reduce C reactive protein and apolipoprotein B. Treating an inflammatory related infection by a known method with the expected result, to reduce inflammation, would have been obvious in view of the above references.

Applicants are claiming a new benefit, whole body health, from an old method, administering to the oral cavity an antimicrobial agent with an H2 antagonist. This benefit may be based on the concept of infection causing inflammation which then through cytokine and other inflammatory cascades, induces a tendency towards inflammation at distant sites. This relationship is old.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4, 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Dependent claims should begin with a definite article.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ralph Gitomer Primary Examiner

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